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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/521,638

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Peter Koch

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2649

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10/08/2008

NOVARTIS  
CORPORATE INTELLECTUAL PROPERTY  
ONE HEALTH PLAZA 104/3  
EAST HANOVER, NJ 07936-1080

EXAMINER

MENON, KRISHNAN S

ART UNIT

PAPER NUMBER

1797

MAIL DATE

DELIVERY MODE

10/08/2008

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/521,638	<b>Applicant(s)</b> KOCH ET AL.	
	<b>Examiner</b> Krishnan S. Menon	<b>Art Unit</b> 1797	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 11 September 2008.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-18 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-18 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                     | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

### **DETAILED ACTION**

Claims 1-18 are pending as amended 9/11/08 in the RCE.

#### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-18 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claim 1 now recites "a method of preparing samples ... comprising the steps of dissolving or dispersing a sample in at least one ionic liquid ... and volatilizing the volatile components of the sample". In this recited method, the 'volatilizing' part is deemed new matter because there is no support for this part in the specification and original claims. While volatilizing is disclosed for the head-space analysis, it is not part of the sample preparation. For the same reason, this step is also not enabling, since if the sample is volatilized during preparation, it may not produce any results during the analysis.

In claim 1, the recitation, “volatilizing ... by headspace gas chromatography” appears to be indefinite, because, headspace gas chromatography is understood as a tool for analysis, not something for evaporating a sample.

***Claim Rejections - 35 USC § 103***

Claims 1-12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Armstrong et al., “Examination of ionic liquids and their interactions with molecules, when used as stationary phases in gas chromatography”, Anal. Chem. 1999, **71**, 3873-3876, (hereinafter: “Armstrong”) in view of JP-4215062 and additional references as evidence listed below.

Claim 1 (currently amended): A method of preparing samples for analysis ~~in headspace gas chromatography~~ comprising the steps of dissolving or dispersing a sample in at least one ionic liquid, wherein the ionic liquid is a molten salt, and volatilizing the volatile components of the sample by headspace gas chromatography.

Applicant’s claims are directed to a method of preparing samples by dissolving or dispersing the sample in an ionic liquid. The dependent claims recite details of the physical properties of the ionic liquids, as well as their chemical compositions.

Armstrong teaches gas chromatography using room-temperature ionic liquids as the stationary phase in the chromatography column, and describes the various ionic liquids. Armstrong teaches that RTILs can solubilize “a number of complex polar molecules”. However, Armstrong does not teach preparing samples by

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dissolving/dispersing in ionic liquids and then volatilizing by headspace gas chromatography.

The JP reference teaches headspace gas chromatography using inorganic salts and/or water as the solvent/dispersion phase, and describes headspace gas chromatography for analyzing aromatics from liquor. The samples are prepared by mixing the liquor in water and/or inorganic salt in a closed container.

Also, the headspace chromatography is well known in the art, and samples for this method are prepared by dissolving or dispersing the material to be analyzed in a suitable solvent/solvent mixture. The choice of the solvent/dispersion medium is based on various factors such as solubility, vapor pressure of the medium, volatility of the component to be analyzed, etc. Further teaching references on this topic for evidence are attached herewith to show that the method of preparing the headspace sample is well known. They are:

(1) Nagai Yumi, Science Links Japan: Analysis of Residual solvents in pharmaceuticals by headspace gas chromatography, Shimadzu review, (2002): this reference teaches that the sample solution is made in a suitable solvent.

(2) Kumar, et al, "Headspace gas chromatography method for the analysis of volatile impurities in hormone replacement trans-dermal patch", Journal of Chromatography A, 859 (1999) 113-118: in this ref, sample is prepared by extracting the material in organic solvents.

(3) Russo: "Static headspace gas chromatography of residual solvents in pharmaceutical products", *Chromatographia* vol 39, no 11/12, December 1994: this reference teaches preparing sample in 2M sodium chloride solution.

Thus, these references and the JP reference teach that the sample for headspace gas chromatography is prepared by dissolving or dispersing the sample material in a suitable solvent or dispersion phase, and can include water, organic solvents, salt solutions, salts, etc. Applicant also implies in paragraphs 5 and 7 (of the Pre-Grant Publication) that method of preparing the sample in solvents is known. The choice of selection of the solvent would be within the skill level of one of ordinary skill in the art. It would be obvious to one of ordinary skill in the art at the time of invention to use the RTILs taught by Armstrong in preparing headspace samples for GC analysis as solvent or dispersant in the well known methods of head-space gas chromatography because of the great advantages of using the ionic liquids as taught by Armstrong (see the introductory paragraphs of Armstrong on page 3873).

### ***Response to Arguments***

Applicant's arguments with respect to claims 1-12 have been considered but are not persuasive.

Since applicant's definition of ionic liquids is very broad, claims directed to the specific ionic liquids presented by the applicant which has not been used for headspace gas chromatography would be allowable as indicated below.

***Allowable Subject Matter***

Claims 13-18 are would be allowable if rewritten to overcome the rejection(s) under 35 U.S.C. 112, 1<sup>st</sup> and 2nd paragraphs, set forth in this Office action and to include all of the limitations of the base claim and any intervening claims. Particularly, claims should be directed at a method of performing headspace gas chromatography, rather than a method of preparing samples.

***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Krishnan S. Menon whose telephone number is 571-272-1143. The examiner can normally be reached on 8:00-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, David R. Sample can be reached on 571-272-1376. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Krishnan S Menon/  
Primary Examiner, Art Unit 1797